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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/780,224

02/09/2001

Petrus W. Roelvink

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09/17/2002

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/780,224

Applicant(s)

ROELVINK ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-48 is/are allowed.
- 6) ☒ Claim(s) 1, 5, 18, 19, 29-32 and 34-40 is/are rejected.
- 7) ☒ Claim(s) 4, 6-17, 20-28 and 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 16
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: *[Signature]*

### Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, 18-19, 29, 30-32 and 34-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Romanczuk et al.

Applicants and Romanczuk et al. (WO 99/36545, published 7/22/99, see whole document, particularly p. 10, lines 18-30; pp. 12-16, p. 19, claims 4, 15-16, 27-28, 41-42, etc.) claim a chimeric pIX protein having at least one pIX domain and a non-native amino acid sequence encoding a ligand (which can be a RGD containing sequence or a sequence capable of binding a target cell) that binds to a substrate present on the surface of a cell, nucleic acids encoding said protein, a adenoviral capsid containing said chimeric pIX, compositions comprising said capsid and a nucleic acid and optionally a liposome, adenoviral vectors comprising said chimeric pIX proteins and a transgene for expression under direction of a non-adenoviral promoter and methods of infecting a cell comprising contacting a cell with said adenoviral vector. Romanczuk et al. therefore teaches the claimed invention.

Applicants traverse this rejection by providing a 37 CFR 1.131 Declaration by Petrus W. Roelvink. The Declaration discloses a DNA construct that encodes an adenoviral pIX protein comprising a non-native amino acid extension at the N terminal of the pIX protein. Applicants argue that the Declaration provides evidence of

conception and reduction to practice of the invention prior to the publication date of the PCT reference. Applicants also assert that the PCT application does not provide guidance as to where to insert the heterologous ligand into the pIX protein so as to generate a functional adenoviral coat protein capable of binding a cellular receptor.

Applicant's arguments filed 4/11/02 have been fully considered but they are not persuasive. First, with regard to the Declaration of Dr. Roelvink, said Declaration is not sufficient to overcome the outstanding 35 USC 102(a) rejection because the evidence presented only discloses a DNA construct encoding a pIX protein with **an uncharacterized N-terminal extension**. Declarant indicates that the construct shows reduction to practice of the subject matter of claim 18. This is not accurate because claim 18 recites a nucleic acid encoding a chimeric pIX protein comprising a sequence encoding a non-native amino acid sequence that is a **ligand that binds a substrate present on a cell surface**. The Declaration provides no evidence that the N-terminal extension encodes a ligand that binds a cell surface substrate. The Declaration provides no evidence of conception and reduction to practice of adenoviral capsids comprising chimeric pIX proteins, chimeric pIX proteins comprising non-native sequences (ligands) inserted into the pIX protein, truncated pIX proteins, adenoviral vectors comprising the recited chimeric pIX proteins, etc.

Second, with regard to applicants' assertion that the PCT application provides no guidance on precisely where in the pIX protein to insert the heterologous ligand so as to generate the recombinant adenoviral capsid, it is noted that the adenoviral capsid proteins (fiber, hexon, penton and pIX proteins) have been well characterized in the art

and Romanczuk et al. provides guidance on assays whereby the binding properties of modified adenoviral capsid proteins can be determined, guidance on how specific cell lines can be used assess infection efficiency of the modified capsids, etc. (See pp. 16-17). It must be considered that the ordinary skilled artisan at the time of applicants' invention would not have needed to conduct any more than routine experimentation in order to reduce to practice the recited chimeric pIX proteins.

Any rejections not repeated in this Office Action are withdrawn.

Claims 41-48 are allowed.

Claims 4, 6-17, 20-28 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 308-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo  
September 12, 2002

DAVID GUZO  
PRIMARY EXAMINER  
*David Guzo*